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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/111,911      | 07/08/1998  | WILLIAM S. M. WOLD   | 16153-5587          | 6287             |

7590 01/02/2002

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1632

DATE MAILED: 01/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/111,911

Applicant(s)

WOLD, WILLIAM S. M.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,7,10,13,14,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 7,10,14 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 4 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Amendment/response filed 10-15-01 has been entered.
2. Claims 3, 6, 12, 17, 19, and 20 have been canceled.
3. Amendments to claims 1, 4, 7, 10, 13, 23, and 24 have been entered.
4. Claims 1, 4, 7, 10, 13, 14, 23, and 24 are pending.

### ***Specification***

5. Submission of figures 6, 9, 11, 12, 24 and 25 is acknowledged.

### ***Claim Objections***

Claims 4 and 13 are objected to because they name the recited adenoviral vector by a number "230-10".

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method of inhibiting apoptosis of a cell, wherein the cell expresses Fas, TNFR-1, DR-3, TRAIL-R1, or TRAIL-2, comprising, contacting the cell with an adenovirus comprising a CMV promoter operably linked to a polynucleotide that encodes a RID $\alpha$  polypeptide, a RID $\alpha$ -L, and a RID $\beta$ , disclosed in SEQ ID NO:1, SEQ ID NO: 2, and SEQ ID NO:4, wherein the adenovirus enters the cell, the RID $\alpha$  polypeptide, a RID $\alpha$ -L, and a RID $\beta$  are expressed in the cell in an amount sufficient to inhibit apoptosis of the cell, the adenovirus lacks at least one functional E1 gene, the cell expresses Fas, DR3, TRAIL-R1, or TRAIL-R2, and the apoptosis is mediated by Fas receptor activity,

does not reasonably provide enablement for other embodiments for reasons of record set forth in the previous office action of 10-15-01.

It is noted that compared with the previously presented claim 10 that recited a method of decreasing apoptosis of target cells in a patient, the applicants have amended claim 10 to recite a method for decreasing the rejection of cells that are transplanted into a patient and therefore, the method is interpreted as a method of treatment wherein cells are transplanted in a patient, the rejection of the cells is decreased, and the cells treat the disease such as degenerative disease or an immunodeficiency disease. As noted in the previous office action of 10-15-01, the specification is not enabling for the claimed invention because the mouse model disclosed in the specification is not an art recognized model of cell or tissue transplantation and rejection.

### ***Response to Arguments***

Applicant's arguments filed 10-15-01 have been fully considered but they are not fully persuasive. It is noted that enablement rejections discussed in the previous office action except for the issue of treatment and the mouse model of the instant application as an art recognized model of transplantation have been dropped. Regarding the issue of treatment, applicants have not presented any arguments. Regarding the issue of the animal model, except for making statements, they have not provided any evidence that the model used in the instant application was an art recognized animal model. While it is not contested that the results disclosed in the specification disclose growth of tumor in the mice, these results are representative of a method of transplanting genetically altered cells in a patient for treating a disease. It is noted that cell graft acceptance depends on a large number of variables including the donor and recipient source, the state of the graft, degree of immunocompatibility between the donor and the recipient etc. and the animal model used in the instant application does not address or include these aspects of the transplantation and therefore, the disclosed model does not represent a model of cell transplantation and rejection. Applicants are advised to

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provide evidence that their model is an art recognized model of cell transplantation or tissue transplantation.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7, 10, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because it does not indicate as to which claim it is dependent on. Accordingly, claim 7 has not been considered on merits.

Claim 10 is indefinite because it recites "which RID complex is operably linked to a cytomegalovirus (CMV) promoter." It is unclear as to how can a polypeptide complex be operably linked to a promoter.

10. Claim 1 is free of the prior art of record and is allowable.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instruction, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.



DAVE T. NGUYEN  
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.